

WHAT IS CLAIMED IS:

1. A holder for a flexible leaflet prosthetic heart valve attachable to a surgical delivery handle, the heart valve having an inflow end and an outflow end and a flow axis therebetween, the valve including an annular sewing ring at the inflow end and a plurality of generally axially-extending commissure posts circumferentially-spaced around the outflow end that support occluding flexible leaflets of the valve, the holder comprising:

a rigid valve abutment portion that contacts the annular sewing ring at the inflow end of the valve,

a shaft member that is axially movable relative to the rigid valve abutment portion between a first position wherein a distal tip of the shaft member is located to the inflow side of the leaflets, and a second position wherein the distal tip is located to the outflow side of the leaflets; and

a plurality of lengths of flexible material extending in a taut fashion across the outflow end of the valve to prevent suture looping, each length of flexible material having first segments extending radially inward from the commissure posts to the shaft member in its second position.

2. The holder of claim 1, wherein in the second position the distal tip of the shaft member extends axially beyond the commissure posts such that each first segment of the lengths of flexible material extends at an angle both radially inward and axially in the outflow direction to the distal tip of the shaft member.

3. The holder of claim 1, wherein the shaft member includes notches on its distal tip for capturing and retaining midpoints of the first segments of the lengths of flexible material, each first segment extending from one of the commissure posts radially inward to the shaft member and then radially outward to an adjacent commissure post via a notch in the shaft member.

4. The holder of claim 1, wherein the valve abutment portion comprises a tubular body having a bore for receiving the shaft member, the shaft member being axially movable within the bore between the first and second positions.

5. The holder of claim 4, further including structure for axially restraining the shaft member in the second position with respect to the valve abutment portion.

5 6. The holder of claim 5, wherein the structure for axially restraining comprises a cantilevered pawl on the shaft member that engages the bore of the valve abutment portion.

7. The holder of claim 4, further including structure for rotationally
10 restraining the shaft member with respect to the valve abutment portion as the shaft member moves between the first and second positions.

8. The holder of claim 1, wherein the valve is of the type that has three
15 leaflets and three commissure posts, and wherein there are three lengths of flexible material and three corresponding first segments, wherein each first segment extends between two commissure posts via the distal tip of the shaft member, and wherein each of the first segments of the three lengths of flexible material mutually crosses over the other two first segments so that each remains along the flow axis of the valve in the first position of the shaft member.

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9. The holder of claim 1, wherein the commissure tips are flexible and extend generally axially in the first position of the shaft member but are cantilevered radially inward by engagement of the shaft member with the lengths of flexible material in the second position of the shaft member.

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10. The holder of claim 1, wherein the lengths of flexible material are secured to the valve abutment portion at both ends.

11. The holder of claim 1, further including a handle interface releasably
30 secured with sutures to the shaft member and having a threaded bore for receiving an

externally threaded boss on a distal end of a surgical delivery handle, the handle interface and delivery handle being disengaged from the shaft member upon severing the sutures.

12. A holder for a tri-leaflet flexible leaflet prosthetic heart valve attachable to a surgical delivery handle, the heart valve having an inflow end and an outflow end and a flow axis therebetween, the valve including an annular sewing ring at the inflow end and three generally axially-extending commissure posts circumferentially-spaced around the outflow end that support occluding flexible leaflets of the valve, the holder comprising:

a shaft member that is axially movable relative to the valve along its flow axis between a first position and a second position, the shaft member having a distal tip; and

three lengths of flexible material extending in a taut fashion across the outflow end of the valve to prevent suture looping, each length of flexible material has a first segment that extends radially inward and mutually crosses over the other two first segments so that each remains along the flow axis of the valve, wherein the distal tip of the shaft member contacts the crossed-over first segments in its second position and displaces them to be angled in the outflow direction.

13. The holder of claim 12, further including a valve abutment portion in contact with the valve sewing ring to which each length of flexible material is secured at both ends.

14. The holder of claim 13, wherein the valve abutment portion comprises outwardly extending brackets for engaging the valve sewing ring, the brackets having through holes therein for receiving and securing the lengths of flexible material.

15. The holder of claim 13, wherein the valve abutment portion comprises a tubular body having a bore for receiving the shaft member, the shaft member being axially movable within the bore between the first and second positions.

16. The holder of claim 15, further including structure for axially restraining the shaft member in the second position with respect to the valve abutment portion.

17. The holder of claim 16, wherein the structure for axially restraining
5 comprises a cantilevered pawl on the shaft member that engages the bore of the valve abutment portion.

18. The holder of claim 15, further including structure for rotationally restraining the shaft member with respect to the valve abutment portion as the shaft
10 member moves between the first and second positions.

19. The holder of claim 12, further including a handle interface releasably secured with sutures to the shaft member and having a threaded bore for receiving an externally threaded boss on a distal end of a surgical delivery handle, the handle interface
15 and delivery handle being disengaged from the shaft member upon severing the sutures.

20. The holder of claim 12, wherein the shaft member includes notches on its distal tip for capturing and retaining the first segments of the lengths of flexible material.

20 21. A holder for a tissue-type prosthetic heart valve attachable to a surgical delivery handle, the heart valve having an inflow end and an outflow end and a flow axis therebetween, the valve including an annular sewing ring at the inflow end and a plurality of generally axially-extending commissure posts circumferentially-spaced around the outflow end that support occluding tissue leaflets of the valve, the holder comprising:

25 a shaft member passing along the axis from the inflow side to the outflow side of the leaflets; and

a plurality of lengths of flexible material extending in a taut fashion across the outflow end of the valve to prevent suture looping, each length of flexible material having first segments extending radially inward from the commissure
30 posts to the shaft member.

22. The holder of claim 21, wherein the shaft member is hollow, and wherein each length of flexible material passes into and through the hollow shaft member.

23. The holder of claim 21, wherein the shaft member is solid and includes
5 notches for capturing and retaining midpoints of the first segments of the lengths of flexible material, each first segment extending from one of the commissure posts radially inward to the shaft member and then radially outward to an adjacent commissure post via a notch in the shaft member.

10 24. The holder of claim 23, wherein the shaft member comprises a wide base on its inflow end and a narrow shaft that passes between and to the outflow side of the leaflets.

15 25. The holder of claim 24, wherein the narrow shaft has a non-circular cross-section.

26. The holder of claim 25, wherein the valve is of the type that has three leaflets and three commissure posts, and the narrow shaft has an equilateral triangular cross-section with the corners of the triangle oriented to point toward the three
20 commissure posts such that the flat sides of the triangle are oriented to abut the three leaflets.

27. The holder of claim 23, the holder further including a rigid valve abutment portion that contacts the annular sewing ring at the inflow end of the valve, the lengths of
25 flexible material each axially extending in second segments along two adjacent commissure posts and attaching to the valve abutment portion at two points such that each length may be severed close to one of its points of attachment to the valve abutment portion and pulled free of the valve along with the valve abutment portion by virtue of its remaining attachment point, the shaft member being rigidly attached to the valve
30 abutment portion.

28. The holder of claim 27, wherein the valve abutment portion includes a mechanism for pulling the second segments toward the valve abutment portion causing the first segments to shorten and the commissure posts to flex inward toward each other.

5 29. The holder of claim 21, wherein the shaft member has an axial length that extends axially beyond the commissure posts such that each first segment of the lengths of flexible material extends at an angle both radially inward and axially in the outflow direction to a distal tip of the shaft member.

10 30. The holder of claim 21, the holder further including a rigid valve abutment portion that abuts the annular sewing ring at the inflow end of the valve, wherein the shaft member is axially movable relative to the valve abutment portion between a first position wherein a distal tip of the shaft member is located to the inflow side of the leaflets, and a second position wherein the distal tip is located to the outflow side of the
15 leaflets.

31. The holder of claim 30, wherein in the second position the distal tip of the shaft member extends axially beyond the commissure posts such that each first segment of the lengths of flexible material extends at an angle both radially inward and axially in
20 the outflow direction to the distal tip of the shaft member.

32. A method for delivering a flexible leaflet prosthetic heart valve, comprising:

providing a flexible leaflet prosthetic heart valve and holder combination,
25 the heart valve having an inflow end and an outflow end and a flow axis therebetween, the valve including an annular sewing ring at the inflow end and generally axially-extending commissure posts circumferentially-spaced around the outflow end that support occluding flexible leaflets of the valve, the holder being releasably attached to the valve sewing ring and having a shaft member that
30 is axially movable relative to the valve along its flow axis between a first position and a second position, shaft member having a distal tip;

attaching a surgical delivery handle to the holder; and

using the handle, axially displacing the shaft member from the first position to the second position so that the shaft member distal end passes from the inflow to the outflow side of the flexible leaflets of the valve and pulls the commissure posts radially inward.

33. The method of claim 32, wherein the holder includes three lengths of flexible material connected thereto and extending in a taut fashion across the outflow end of the valve, each length of flexible material having first segments extending radially inward from the commissure posts to the valve flow axis such that the shaft member contacts the first segments in its second position and increases the tension therein to pull the commissure posts radially inward.

34. The method of claim 33, wherein each first segment mutually crosses over the other two first segments so that each remains along the flow axis of the valve.

35. The method of claim 32, further including rotating the shaft member with the handle prior to axial displacement.

36. The method of claim 35, further including locking the shaft member in its second position.

37. The method of claim 32, wherein the holder further includes a handle interface to which the handle attaches, the method including detaching the handle from the holder by severing sutures connecting the handle interface to the rest of the holder.